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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,935	12/21/2000	Timothy Raymond Hirst	9274	8699

7590 07/26/2004

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/674,935

Applicant(s)

HIRST ET AL.

Examiner

Khatol S Shahnian-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 6-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' response and amendment of 5/20/2004 are acknowledged. Claims 1 and 3-5 have been amended. Claim 2 has been canceled. Specification page 1 has been amended.
2. Claims 1 and 3-37 are pending in this application. Claims 6-37 are withdrawn from consideration as being drawn to non-elected inventions.
3. Claims 1 and 3-5 are under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Objections Withdrawn

6. Objection to the abstract of disclosure made in paragraph 6 of the office action mailed 11/17/2003 is withdrawn. Applicants have submitted an abstract on a separate page.
7. Objections to the specification made in paragraphs 7 and 8 of the office action mailed 11/17/2003 are withdrawn in view of applicants' amendments and arguments.

Rejections Moot

8. Rejection of claim 2 under 35 U.S.C. 112 second paragraph made in paragraph 11 of the office action mailed 11/17/2003 is moot in view of applicants' cancellation of said claim.

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9. Rejection of claim 2 under 35 U.S.C. 103(a) made in paragraph 17 of the office action mailed 11/17/2003 is moot in view of applicants' cancellation of said claim.

Rejections Withdrawn

10. Rejection of claims 1 and 3-5 under 35 U.S.C. 112 first paragraph made in paragraph 11 of the office action mailed 11/17/2003 is withdrawn in view of applicants' amendments and data provided.

11. Rejection of claims 1 and 3-5 under 35 U.S.C. 112 second paragraph made in paragraph 13 of the office action mailed 11/17/2003 is withdrawn in view of applicants' amendments.

Objections Maintained

12. Objection to the specification made in paragraph 9 of the office action mailed 11/17/2003 is maintained.

The objection was as stated below:

Numerous abbreviations have been noted in the specification without reference to their full names. Appropriate corrections are required.

Applicants have addressed this issue in the response filed 5/20/04. Applicants have asked the examiner to identify the abbreviations which are not well-known that require definition.

The examiner respectfully draws applicants attention to page 34, line 17 of the specification for the definition of MLN and CLN.

Rejections Maintained

13. Rejection of claim 1 under 35 U.S.C. 102(b) made in paragraph 9 of the office action mailed 11/17/2003 is maintained.

The rejection was as stated below:

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Holmgren et al. (US 5,681,571).

Claim 1 is drawn to a method for stimulating an immune response to a composition against an infectious disease caused by an infectious agent comprising administering to a subject an effective amount of an immunomodulator containing E.coli heat labile enterotoxin (EtxB) or B subunit of cholera toxin (CtxB).

Holmgren et al. teach a method for stimulating an immune response to a composition against an infectious disease caused by an infectious agent comprising administering to a subject an effective amount of an immunomodulator containing E.coli heat labile enterotoxin (EtxB) or B subunit of cholera toxin (CtxB) see claim 1.

Applicants argue that Holmgren et al. teach inducing immunological tolerance and do not teach stimulating an immune response.

Applicants' arguments have been fully considered but they are not persuasive.

Holmgren et al. teach stimulating an immune response to CtxB (see columns 2 and 5).

Therefore, the prior art anticipates the claimed invention.

14. Rejection of claims 1 and 3-5 under 35 U.S.C. 103(a) made in paragraph 17 of the office action mailed 11/17/2003 is maintained.

The rejection was stated below:

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clements (US 6,413,523 B1) in view of Marcello et al. (Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 8994-8998, September 1994).

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Claims are drawn to a method for stimulating an immune response to a composition against an infectious disease caused by herpes virus comprising administering to a subject an effective amount of an immnuomodulator containing E.coli heat labile enterotoxin (EtxB).

Clements teaches a method for stimulating an immune response to a composition against an infectious disease caused by herpes virus comprising administering to a subject an effective amount of an immnuomodulator containing E.coli heat labile enterotoxin (EtxB) see abtstract and claims specially claims 1, 9 and 10. Clements does not teach an agent other than EtxB having GM 1 binding activity. However, Marcello et al. teach an agent other than EtxB having GM 1 binding activity (see abstract and left column in page 8995and left column in page 8997). At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the methods taught by Clements and Marcello et al. due to teaching of Clements that E.coli heat labile enterotoxin can be used in combination with an unrelated antigen to achieve a higher immune response (see abstract) to combine EtxB with an agent other than EtxB.

Applicants argue that Clements has been used as prior art by the applicants and does not disclose, teach or suggest stimulating immune response by the subunit EtxB rather the reference teaches the whole toxin E.coli heat labile enterotoxin (LT). Applicants further argue that Marcello et al. teach the EtxB that is linked to a specific peptide and not administered freely with a vaccine.

Applicants' arguments have been fully considered but they are not persuasive. It is the examiner's position that it appears that the applicants argue against the references individually.

In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated in the rejection above Clements teaches a method for stimulating an immune response to a composition (i.e a vaccine) comprising an immunomodulator containing Etx (see abstract and claims). Marcello et al. teach EtxB (see abstract). The combination of the references teach the claimed invention.

Conclusion

15. No Claims are allowed.

16. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

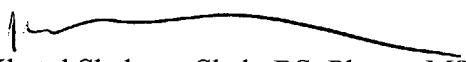
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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

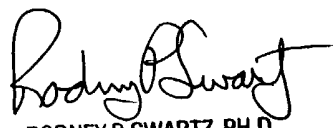
Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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July 21, 2004


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER